UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Provigil, Nuvigil

Program	Prior Authorization
Medication	Provigil, Nuvigil
Issue Date	2/2010
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

1. Background:

Modafinil (Provigil) and armodafinil (Nuvigil) are wakefulness-promoting agents for oral administration. Both products are approved by the Food and Drug Administration (FDA) to improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work disorder. Modafinil has been shown to be beneficial in the treatment of excessive sleepiness in patients with idiopathic hypersomnia, treatment of fatigue associated with multiple sclerosis, and in the augmentation therapy for the treatment of depression.

2. Coverage Criteria:

A. Narcolepsy, Obstructive Sleep Apnea, or Shift Work Disorder

1. Authorization Criteria

a. **One** of the following:

- Diagnosis of narcolepsy
- Diagnosis of excessive sleepiness due to obstructive sleep apnea
- Diagnosis of excessive sleepiness due to shift work disorder (circadian rhythm sleep disorder, shift work type)

-AND-

b. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

B. Fatigue due to MS (off-label)

1. Initial Authorization

a. Diagnosis of multiple sclerosis (MS)

-AND-

b. Patient is experiencing fatigue

-AND-

c. Used in combination with standard educational therapies (e.g., psychoeducation, behavioral programs, scheduled naps, additional non-pharmacological therapies, etc)

-AND-

d. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

2. Reauthorization

a. Patient is experiencing relief of fatigue with therapy

-AND-

b. Used in combination with standard educational therapies (e.g., psychoeducation, behavioral programs, scheduled naps, additional non-pharmacological therapies, etc)

-AND-

c. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

C. Idiopathic Hypersomnia (off-label)

1. Initial Authorization

a. Diagnosis of idiopathic hypersomnia as confirmed by sleep study (unless the prescriber providers justification confirming that a sleep study would not be feasible)

-AND-

b. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to therapy

-AND-

b. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

D. Adjunctive Therapy for the Treatment of Major Depressive Disorder or Bipolar Depression (off-label)

1. Initial Authorization

a. Treatment-resistant depression, defined as both of the following:

(1) Diagnosis of one of the following:

- Major depressive disorder (MDD)
- Bipolar depression

-AND-

(2) History of failure, contraindication, or intolerance to at least two antidepressants from different classes (e.g., SSRIs, SNRIs, bupropion)

-AND-

b. Used as adjunctive therapy

-AND-

c. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

2. Reauthorization

   a. Documentation of positive clinical response to therapy

   -AND-

   b. Used as adjunctive therapy

   -AND-

   c. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

4. References

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Program	Prior Authorization- Provigil, Nuvigil
Change Control	
Date	Change
2/2010	New policy
9/2010	Removed requirement of the trial of Provigil prior to Nuvigil approval.
6/2011	Annual Review. Added Nuvigil indications to section II, Indications. No criteria changes.
6/2012	Annual Review. Added generic requirement for Provigil in product list table.
6/2013	• Converted policy to new UHC enterprise wide formatting. • Added additional confirmation symptoms for OSA initial therapy (see sections 1.1 and 2.1 of OSA initial therapy) • Created reauthorization criteria for SWSD • Added requirement for MS fatigue that requires combination with

	standard educational therapies • Created reauthorization criteria for MS fatigue • Created quantity limit exception criteria for both Provigil and Nuvigil • Created reauthorization criteria for Narcolepsy • Seperated Narcolepsy and Idiopathic Hypersomnia criteria • Created reauthorization criteria for and Idiopathic Hypersomnia
9/2013	• For Provigil/Nuvigil, revised narcolepsy criteria from "submission of sleep study confirming diagnosis of narcolepsy" to "diagnosis of narcolepsy as confirmed by sleep study" • For Provigil, revised idiopathic hypersomnia criteria from "submission of sleep study confirming diagnosis of idiopathic hypersomnia" to "diagnosis of idiopathic hypersomnia as confirmed by sleep study"
12/2014	Added prior authorization criteria for Provigil (modafinil) for adjunctive treatment for the treatment of major depressive disorder or bipolar depression
10/2016	Updated policy template. A few of the AND statements were changed to OR statements in the quantity limit section.
12/2016	Updated wording in quantity limit sections
3/2017	Changed all authorization durations to 12 months.
8/2017	Updated clinical criteria to only diagnosis for narcolepsy, obstructive sleep apnea, and shift work disorder and trial/failure of armodafinil if requesting modafinil. Removed quantity limit sections. Changed Provigil to modafinil throughout policy. Updated background.
3/2018	Modified the language around the diagnosis for shift work disorder to include circadian rhythm, shift work disorder, to match the ICD10 code. Updated off-label sections to allow for use of armodafinil.